UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,583	02/08/2007	Sayoko Matsumoto	09812.0126	3961

22852 7590 12/11/2008

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
12/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,583	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *5-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/13/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Please note that the Examiner handling this Application has changed and is now Stephen Kapushoc in Art Unit 1634. Please address any future correspondence regarding this Application to the above named Examiner.

Claims 1-13 are pending.

Claims 5-10 remain withdrawn from examination as detailed in the previous Office Action.

Claims 1-4 and 11-13 are examined on the merits.

This Office Action is in reply to Applicants' correspondence of 08/04/2008.

Applicants' remarks and amendments have been fully and carefully considered but are not found to be sufficient to put the application in condition for allowance. Any new grounds of rejection presented in this Office Action are necessitated by Applicants' amendments. Any rejections or objections not reiterated herein have been withdrawn in light of the amendments to the claims or as discussed in this Office Action.

This Action is made **FINAL**.

Please note: The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Claim Rejections - 35 USC § 112 2nd ¶ - Indefiniteness

1. The rejections of claims under 35 USC 112 2nd ¶ as set forth on pages 2-4 of the previous Office Action are **WITHDRAWN** in light of the amendments to the claims.

Withdrawn Claim Rejections - 35 USC § 102

2. The following rejections under 35 USC 102, as set forth in the previous Office Action (pages 4-6) are **WITHDRAWN:**

The rejection of claims as anticipated by Lee (Lee, et al. IEEE-NANO 2003, Third IEEE Conference on Nanotechnology, 12-14 Aug. 2003; .2: 729-732), in light of the amendments to the claims.

The rejection of claims as anticipated by Chou (Chou, et al. Biophys J. 2002 October; 83(4): 2170–2179) in light of the amendments to the claims.

Withdrawn Claim Rejections - 35 USC § 103

3. The following rejections under 35 USC 103, as set forth in the previous Office Action (pages 6-12) are **WITHDRAWN:**

The rejection of claims as obvious in light of the teachings of Lee (Lee, et al. IEEE-NANO 2003, Third IEEE Conference on Nanotechnology, 12-14 Aug. 2003; .2: 729-732), in light of the amendments to the claims.

The rejection of claims as obvious in light of the teachings of Segawa (Segawa, et al. US PGPub 20060127904, published 6/15/06, filed 8/20/03), in light of the amendments to the claims and the presentation of a certified translation of the foreign priority document (JP No.2003-346779, 10/6/03).

The rejection of claims as obvious in light of the teachings of Segawa (Segawa, et al. US PGPub 20060127904, published 6/15/06, filed 8/20/03) in view of Lee (Lee, et al. IEEE-NANO 2003, Third IEEE Conference on Nanotechnology, 12-14 Aug. 2003; .2: 729-732), in light of the amendments to the claims and the presentation of a certified translation of the foreign priority document (JP No.2003-346779, 10/6/03).

New Claim Rejections - 35 USC § 103

4. Claims 1-4 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Namasivayam et al (2002) in view of Lee et al (2002) (citation 'U' on PTO-892 of 04/01/2008).

Namasivayam et al teaches methods of stretching nucleic acid molecules. Relevant to the limitations of independent claim 1, the reference teaches: providing a reaction detecting section including a first electrode, a seconded electrode, and a reaction well sandwiched between the electrodes (Fig 7a); a reaction system with a solution of pH 5 to 11 (p.3380, left col., lns.9-26); and a first electrode having a surface area smaller that that of the second electrode (Fig 7b; Fig 9). The reference further teaches that without application of an electric current, the nucleic acid is in a coiled form, thus teaching adding a nucleic acid in a coil form (e.g. legends of Figs 5, 6, and 9). The reference teaches applying an ac voltage of high frequency to the electrodes, which forms an electric field and stretches the nucleic acid (e.g.: p.3380 – Application of electric fields; Fig. 9).

Relevant to the limitations of claim 2, Namasivayam et al teaches a frequency of 1MHz (p.3384, left col., ln.11), and specifically teaches amplitudes of 0.3 V/μm and 1.0 V/μm (e.g.: p.3378 – Abstract; p.3378, right col., lns.21-25; Fig 9).

Relevant to the limitations of claims 3 and 13, Namasivayam et al teaches separation of electrodes by a distance of 20 μm, which is a distance such that no convection is induced in the solution (e.g. p.3384, left col. ln.7 – right col. ln.2).

Relevant to the limitations of claim 4, Namasivayam et al teaches dielectrophoretic migration of the nucleic acid toward the first electrode (e.g.: Fig 5; Fig 9; p.3378, right col., lns.12-28; p.3383 – Effect of electric field).

Relevant to the limitations of claim 11, Namasivayam et al teaches fixing an end of the nucleic acid to the first electrode (e.g.: p.3382, left col., lns.6-20; Fig 9).

Namasivayam et al does not specifically teach the stretching of a single stranded nucleic acid (as recited in claim 1), does not specifically recite that the solution in the reaction well is an aqueous solution (as recited in claim 1) comprising pure water (as reited in claim 12), and does not specifically teach an amplitude of 1.2 V/μm.

However such limitations were well known in the art at the time the invention was made.

Lee et al teaches the manipulation of nucleic acids in electric fields. Relevant to the limitations of claims 1 and 12, Lee teaches separation of single-stranded DNA (ssDNA, as required by claim 1) in a stretched form in pure water (which is an aqueous solution, as require by claim 1 and 12) for deposition of the ssDNA onto electrodes (p.731, left col.) Relevant to the limitations of claim 2, Lee et al teaches that the frequency of the AC electric field was 5MHz (i.e. high frequency) and the voltage was 0.82V/μm (pg 730, left col.).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have analyzed the ssDNA of Lee et al using the methods of Namasivayam et al. One would have been motivated to analyze ssDNA based on the assertion of Lee et al regarding the importance of the analysis of

interactions including ssDNA (e.g. p.730, right col., lns.1-13). It would have been further obvious to perform the methods of Namasivayam et al specifically with an aqueous solution, as taught by Lee et al, where one would have been motivated to use an aqueous solution based on the successful analysis of nucleic acids in aqueous solutions as taught by Lee et al.

Regarding the limitations of claim 2, while Namasivayam et al teaches amplitudes of 0.3 V/μm and 1.0 V/μm and Lee et al teaches an amplitude of 0.82V/μm, neither Namasivayam et al nor Lee et al particularly teaches an amplitude of 1.2V/μm or higher.

However, the MPEP teaches "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons,

there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.).

Therefore, it would have been prima facie obvious to the ordinary artisan and the ordinary artisan would have been motivated to modify the method of Namasivayam et al in view of Lee et al by adjusting the voltage amplitude as part of standard optimization practices in the art.

There is a reasonable expectation of success because it is common practice in the art to adjust the general conditions of an experiment as a routine means of optimization.

Withdrawn Double Patenting Rejection

5. The rejection of claims 1 and 4 as being unpatentable over claim 29 of copending Application No. 10535714 is withdrawn in light of the amendments to the claims.

Conclusion

6. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days.

Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Stephen Kapushoc/
Art Unit 1634

/Jehanne S Sitton/
Primary Examiner, Art Unit 1634